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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,956	06/08/2005	William T McAllister	R1401-100-US	1385

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HOFFMAN WARNICK & D'ALESSANDRO, LLC  
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EXAMINER
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FREDMAN, JEFFREY NORMAN

ART UNIT	PAPER NUMBER
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1637

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/17/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/537,956

Applicant(s)

MCALLISTER ET AL.

Examiner

Jeffrey Fredman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 February 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 5,6 and 8-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4,7,16 and 17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>6/8/05</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election of Group I, Species III in the reply filed on February 13, 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 5, 6 and 8-15 are withdrawn from further prosecution.

### ***Claim Rejections - 35 USC § 112 – Written Description***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-4, 16 and 17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

### **Legal Analysis**

In analysis of the claims for compliance with the written description requirement of 35 U.S.C. 112, first paragraph, the written description guidelines note regarding genus/species situations that "Satisfactory disclosure of a ``representative number" depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed." (See: Federal Register:

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December 21, 1999 (Volume 64, Number 244), revised guidelines for written description.)

All of the current claims encompass a genus of RNA polymerases which are different from those disclosed in the specification, since the claims are drawn to any RNA polymerase which functions in having a significantly diminished ability to displace RNA with a region that is a "disordered loop".

The genus includes variants for which no written description is provided in the specification. This large genus is represented in the specification by only three species, the 172-173 deletion mutation in T7 RNA polymerase, the 173-174 deletion mutation in T3 RNA polymerase and the 140-143 deletion mutation in the SP6 polymerase. Thus, applicant has express possession of only three particular sequences in a genus which comprises hundreds of trillions of different possibilities.

It is noted in the The Regents of the University of California v. Eli Lilly and Co. 43 USPQ2d 1398 (Fed. Cir. 1997) that,

"A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. See *Fiers*, 984 F.2d at 1169- 71, 25 USPQ2d at 1605- 06 (discussing *Amgen*). It is only a definition of a useful result rather than a definition of what achieves that result. Many such genes may achieve that result. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736 F.2d 1516, 1521, 222 USPQ 369, 372- 73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. "

In the current situation, the definition in claim 1 of an RNA polymerase with a reduced ability to displace RNA is entirely functional. Even the limitation in claim 4, where there is a region with a "disordered loop" does not impose any significant structure on the biological molecule. This is precisely the situation of naming a type of material which is generally known to likely exist, but is in the absence of knowledge of the material composition of more than the three species expressly disclosed. This is entirely a definition by function.

It is noted that in Fiers v. Sugano (25 USPQ2d, 1601), the Fed. Cir. concluded that

"...if inventor is unable to envision detailed chemical structure of DNA sequence coding for specific protein, as well as method of obtaining it, then conception is not achieved until reduction to practice has occurred, that is, until after gene has been isolated...conception of any chemical substance, requires definition of that substance other than by its functional utility."

Based on this legal analysis, the specification lacks a representative number of species of RNA polymerases.

**Absence of a representative number of species**

In the current case, the generic claim is to any RNA polymerase, with the claimed function, irrespective of the structure. The genus of nucleic acids represents every possible variation which could occur in any RNA polymerase that would yield the desired function. In order to provide a representative number of species, the court in Lilly required "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the

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members of the genus, which features constitute a substantial portion of the genus.

Lilly at 1406. Here, only three species are disclosed and these species do not represent a substantial portion of the genus of all bacteriophage RNA polymerases.

According to Science News Online (see

<http://www.sciencenews.org/articles/20030712/bob9.asp>), "Almost as staggering as the number of bacteriophages is their genetic diversity, according to scientists at the microbiology meeting. "Phages are probably the most diverse things on the planet," says Forest Rohwer of San Diego State University." The article further notes that ""We guarantee them that the bacteriophage they find will never have been discovered before. We know that because the diversity is so high, and we've never isolated the same bacteriophage twice," says Hatfull." Given this immense diversity, there is no expectation in the instant case of insubstantial variation in the claimed genus. In fact, there is no reason to believe that the three species are representative of the millions of different bacteriophages.

### **Conclusion**

In the application at the time of filing, there is no record or description which would demonstrate conception of the variants of bacteriophage RNA polymerases which meet the functional requirements of claims 1-4. Therefore, the claims fail to meet the written description requirement by encompassing sequences which are not described in the specification.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-4, 7, 16 and 17 are rejected under 35 U.S.C. 102(e) as being anticipated by Watahiki et al (U.S. 2004/0259089).

Watahiki teaches a mutant SP6 RNA polymerase with nucleotides 140-143 deleted (see paragraph 0069). Watahiki also teaches the T7 RNA polymerase with the 172-173 deletion (see paragraph 0072) and the T3 RNA polymerase with the deletion at 173-174 (see paragraph 0064).

With regard to claims 1-4, 16 and 17, since Watahiki teaches an RNA polymerase that is identical in structure to the RNA polymerase being claimed (see paragraph 0069, for example), Watahiki inherently anticipates these claims.

With regard to claim 7, Watahiki teaches a mutant SP6 RNA polymerase with nucleotides 140-143 deleted (see paragraph 0069).

6. In the interest of compact prosecution, since claims 1-4, 16 and 17 are generic, the rejection over Lyakhov will also be made.

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7. Claims 1-4, 16 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Lyakhov et al (J. Mol. Biol. (1997) 269:28-40).

Lyakhov teaches a mutant T7 RNA polymerase with the 172-173 deletion (see page 31, table 1) and the T3 RNA polymerase with the deletion at 173-174 (see page 31, table 1).

With regard to claims 1-4, 16 and 17, since Lyakhov teaches an RNA polymerase that is identical in structure to the RNA polymerase being claimed (see page 31, table 1, for example), Lyakhov inherently anticipates these claims.

### ***Conclusion***


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is (571)272-0742. The examiner can normally be reached on 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571)272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Jeffrey Fredman  
Primary Examiner  
Art Unit 1637

3/16/07